## REMARKS

A. Request for Reconsideration

Applicant has carefully considered the matters raised by the Examiner in the outstanding Office Action but remains of the position that patentable subject matter is present. Applicant respectfully requests reconsideration of the Examiner's position based on the amendments to the claims and the following remarks.

B. The Invention

The present invention is directed to a process for the separation, identification and quantification of individual microbes in a mixture of microbes using electrokinetic separation systems.

In one of the novel aspects of the invention, the microbes are separated in a fluid that contains a dilute water soluble polymer. The dilute water soluble polymer affects the migration time and the mobility of the microbes in the mixture thereby providing a fast and accurate identification of the microbes.

In another novel aspect of the invention, the microbes are separated by capillary isoelectric focusing.

C. Claim Status and Amendments

Claims 1, 3-6, 8-13, 15, 17 and 22-29 are presented for further prosecution. Claims 2, 7, 14 and 16 have been canceled and claims 18-21 have been withdrawn from consideration.

Claims 1, 6, 10 and 15 have been amended to recite that separating is performed by capillary electrophoresis using a fluid that contains a dilute water soluble polymer. Support for these amendments can be found at page 14, paragraphs 3-4.

New claims 22-25 have been added to define the water soluble polymer. Support for these new claims can be found at page 14, paragraph 3.

New claims 26-29 have been added to mirror original claims 1, 6, 10 and 15, except that claims 26-29 recite that the microbes are separated by capillary isoelectric focusing using a fluid that contains an ampholyte. Support for new claims 26-29 can be found at page 15, paragraph 2 and in original claims 1, 6, 10 and 15.

D. Affirmation of Election

Applicant affirms the provisional election of Group I, claims 1-17 made February 2, 2005.

E. The Office Action

The Examiner had made 9 rejections against the independent claims. Claims 1-4 had been rejected as being anticipated by Ebersole (US 5,578,460). Claims 1-5 had been rejected as being anticipated by Durr (US 5,723,031). Claims 1-4 had been rejected as being anticipated by Armstrong (Separating...Molecules). Claims 1-9 had been rejected as being anticipated by Sablovic (FR 2468120). Claims 1-4 had been rejected as being unpatentable over Yueng (US 5,006,210). Claim 5 had been rejected as being unpatentable over Ebersole in view of "Streptococcus pyogenes" and "The Bacteria Antibiotics Can't Kill". Claim 5 had been rejected as being unpatentable over Armstrong in view of Armstrong and "TSCA...fact sheet". Claims 6-14 had been rejected as being unpatentable over Durr. Finally, claims 15-17 had been rejected as being unpatentable over McCormick (US 6,613,211).

1. The Armstrong publication

Applicant is a co-author of the Armstrong publication cited as prior art.

According to MPEP § 715.01(c), a publication that is not a statutory bar may be overcome by a showing that the

publication was published by Applicant or on his/her behalf.

Enclosed is a Declaration indicating that Applicant is the sole inventor of the subject matter disclosed in the publication and disclosed and claimed in this Application, and that the other co-authors were merely working under his direction. It is deemed that the Armstrong publication is no longer prior art.

2. The novel effects of the present invention

The electrokinetic separation processes of the present invention have significant advantages over the art due to the presence of the dilute water soluble polymer in the fluid during electrophoresis, and due to the presence of the ampholyte in the fluid during isoelectric focusing.

First, the dilute polymer and the ampholyte function to compress or focus the band peak of the electropherogram. As a result, different types of microbes are separated from one other, while the same types of microbes are compressed together to form a sharp microbial peak away from the electroosmotic flow front. The specific types of microbes in the mixture can be accurately identified by the sharp peaks as shown in Figure 2 of the Application.

Second, the dilute polymer and the ampholyte in the fluid provide fast migration times which allow for shorter capillaries that are beneficial in microchip-type devices. Figures 2, 5 and 6 show desirable migration times of less than 15 minutes.

3. Ebersole does not suggest capillary electrophoresis using a dilute water soluble polymer or capillary isoelectric focusing using an ampholyte

Ebersole teaches an electrophoretic separation process for microbes and cell populations. As shown in Figures 6-10 of Ebersole, different microbes can be separated from a mixture of microbes.

The electrophoretic process of Ebersole differs from the electrophoretic process of the present invention since Ebersole does not disclose the presence of a dilute water soluble polymer in the fluid as recited in claims 1, 6, 10 and 15. As explained in section 2 above, the dilute water soluble polymer a) provides sharp peaks in the electropherogram which allow for an accurate identification of microbes, and b) provides fast migration times.

Ebersole does not disclose the presence of a dilute water soluble that provides sharp peaks and fast migration times. As shown in Figures 6-10 of Ebersole, the different

microbe peaks are much wider and broader than the very narrow and sharp peaks of Figures 2, 5 and 6 of the Application. For example, 4 sharp microbial peaks are shown within a 5 minute window in Figure 2 of the Application (between 5 and 10 minutes on the X-axis), while 4 broad microbial peaks are shown within a 30 minute window in Figure 8 of Ebersole (between 50 and 80 minutes on the X-axis). The comparison between Figure 2 of the Application and Figure 8 of Ebersole shows that the present invention a) provides sharp peaks in the electropherogram compared to Ebersole and b) provides fast migration times compared to Ebersole. The novel effects of claims 1, 6, 10 and 15 are due to the presence of the dilute water soluble polymer in the fluid during capillary electrophoresis. Respectfully, Ebersole does not teach or suggest the claimed process or its superior results.

Applicant wishes to note that Ebersole discloses a polymer in the fluid at col. 15, lines 2-5. However, Ebersole adds the polymer to "alter the viscosity". Thus, the polymer of Ebersole is not a dilute polymer as claimed. A dilute polymer does not alter the viscosity to a substantial degree.

As indicated by the final sentence in column 1 at page 5526 of the enclosed publication entitled "Mechanistic

Aspects in...Electrokinetic Separations", an increased viscosity (as taught by Ebersole) "decreases the EOF" and "plays no role in focusing or compressing the injected microbe sample". Thus, according to the teachings of Ebersole, adding a polymer to increase the viscosity does not achieve the compressed microbial peaks of the present invention. Applicant respectfully submits that the dilute polymer of the present invention is not obvious based on the teachings of Ebersole.

Finally, with regard to claims 26-29, Ebersole does not suggest a capillary isoelectric focusing method using an ampholyte. Similar to the dilute polymer explained above, the ampholyte focuses the microbes in the fluid to obtain a sharp peak in the electropherogram (page 15, paragraph 2). First, Ebersole does not suggest a capillary isoelectric focusing method. Second, Ebersole does not suggest the ampholyte for the isoelectric method that obtains the sharp peaks. Respectfully, claims 26-29 are patentable over Ebersole.

4. Durr, Sablovic, Yueng and McCormick do not suggest a process for separating different microbes from a mixture of microbes

Durr teaches a process for separating viruses from biological material, not from other viruses. For example, Durr separates viruses from proteins and nucleotides (col. 2, lines 34-36). Figure 2 of Durr shows that the first peak identifies the nucleotides, while the second peak identifies the proteins (col. 5, lines 32-35).

Durr does not suggest a process for separating microbes from other microbes as recited in the independent claims. In addition, Durr does not suggest the dilute polymer of claims 1, 6, 10 and 15 or the isoelectric focusing method of claims 26-29 using the ampholyte. It is submitted that the claimed invention patentable over Durr.

Sablovic teaches a device where particles are electrokinetically pumped through a tube. A detector detects the particles in the tube using spectral analysis. In short, Sablovic uses an the electrophoretic mobility of the particles to move the particles through a tube for identification.

In contrast to the present invention, the device of Sablovic does not separate microbes from other microbes as recited in the claims. Sablovic merely pumps particles

through a tube and identifies the particles one at a time. Furthermore, the fluid of Sablovic does not contain the claimed dilute polymer or the claimed ampholyte. Respectfully, the present invention is patentable over Sablovic.

Yueng discloses a device for capillary electrophoresis using a laser-induced fluorescence detector. The laser detector of Yueng detects microbes that travel through the capillary (col. 3, lines 46-66).

Yueng does not suggest the dilute polymer of claims 1, 6, 10 and 15, or the isoelectric focusing method of claims 25-29 using the ampholyte. As explained in section 2 above, the dilute polymer and the ampholyte a) provide sharp peaks in the electropherogram which allow for an accurate identification of microbes, and b) provide fast migration times. Yueng does not suggest these aspects of the claimed invention. Respectfully, the present invention is patentable over Yueng.

McCormick discloses a method of capillary electrophoresis where the cells are interacted with agents to allow for detection of the cells. The interaction is a physical interaction, where the agent is bound to the cell, the cell is physiologically changed, destroyed, divided or otherwise changed (col. 2, lines 60-65).

In contrast to McCormick, the dilute polymer and the ampholyte of the present invention do not physically alter the microbes. Rather, the dilute polymer and the ampholyte separate different microbes from the electroosmotic flow front without physically damaging the cells. In fact, the independent claims recite processes for separating the microbes while maintaining the microbes intact. It is respectfully submitted that the dilute polymer and the ampholyte are not suggested by McCormick.

5. The remaining references

The remaining publications cited by the Examiner do not suggest the claimed electrophoresis and isoelectric focusing processes of the present invention using the dilute polymer or the ampholyte. It is submitted that the present invention is patentable over all the cited references taken alone or in combination.

F. New Claim Fees

PTO 2038 is enclosed to cover the fee for the additional claims.

G. Conclusion

In view of the foregoing and the enclosed, it is respectfully submitted that the application is in condition for allowance and such action is respectfully requested. Should any extensions of time or fees be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit Account # 02-2275.

Respectfully submitted,

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Encl: - Declaration of Inventorship
- Copy of publication entitled "Mechanistic Aspects in the Generation of Apparent Ultrahigh Efficiencies for Colloidal (Microbial) Electrokinetic Separations, Analytical Chemistry, Vol. 74, No. 21, November 1, 2002.